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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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William R. Freeman

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EXAMINER

HUANG, GIGI GEORGIANA

ART UNIT

PAPER NUMBER

1612

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/531,546	Applicant(s) FREEMAN, WILLIAM R.	
	Examiner GIGI HUANG	Art Unit 1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 May 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12, 14-37 and 40-42 is/are pending in the application.
- 4a) Of the above claim(s) 19-23, 25-40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12, 14-18, 24, 41 and 42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Application

1. The response filed May 5, 2009 has been received, entered and carefully considered. The response affects the instant application accordingly:
 - a. Claims 11-12 have been amended.
 - b. Claim 13 has been cancelled.
2. Claims 1-12, 14-37, 40-42 are pending in the case.
3. Claims 1-12, 14-18, 24, 41-42 are present for examination.
4. The text of those sections of title 35.U.S. Code not included in this action can be found in the prior Office action.
5. All grounds not addressed in the action are withdrawn or moot.
6. New grounds of rejection are set forth in the current office action.

New Grounds of Rejection

7. Due to the amendment of the claims the new grounds of rejection are applied:

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 11-12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. The claims are directed to the use of an

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automated image analysis. There is no support in the original disclosure for the term.

There is no description in the specification to address what systems are automated and which are not, nor if it is an issue of degree wherein what degree or portion of the analysis is automated. This is a new matter rejection.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 11-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are indefinite as it is unclear what the term "automated image analysis" designates as there is no description in the specification as addressed above. As image analysis such as the SLO utilizes computer processing, for purposes of prosecution any image analysis applies.

Response to Arguments

10. Claims 1-3, 6-11, 13-18, 24, 41-42 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement in regards the term "photosensitizer".

Claim 13 is cancelled, the rejection is moot.

Applicant's arguments filed 5/5/2009 have been fully considered but they are not persuasive. Applicant asserts that then specification is clear on what a photosensitizer encompasses citing certain paragraphs of the specification. This is not persuasive as

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the paragraphs cited state that it can be any compound capable of activation by light radiation resulting in destruction of the surrounding tissue and the remaining description are directed to preferred embodiments but as the term is to directed to a function description of what it does and not what it is as cited by the claims, it does not provide adequate description as to the level of binding or degree of activation and absorption of EM radiation including compounds yet to be found. This is evident in compounds that are being test, found, and described in Wharton et al. (2009/0076115) wherein new photosensitive fullerenes are taught that also have antimicrobial activity (abstract, paragraph 6-7); and Zheng et al. (U.S. Pat. Pub. 2008/0253960) who teaches the use of clonogenic assays to assess and develop new photosensitive compounds such as (tBu).sub.4SiPc-BOA which are new and in a lipid core (paragraph 173-174) which were developed after the filing date of the instant application and was not in possession of Applicant at the time of filing.

Accordingly, the rejection is maintained.

11. Claims 1-11, 13-18, and 24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for the term "greater than about 50j/cm²". The term "greater than about" is a relative term that renders the claims indefinite

Claim 13 is cancelled, the rejection is moot.

Applicant's arguments filed 5/5/2009 have been fully considered but they are not persuasive. Applicant's argument is that the specification gives a clear range for the degree of "about" and the reference to MPEP 2173.05(b) that "exceeding about 10% per second" is not indefinite. This is not persuasive as the arguments for "about" is not

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commensurate in scope with the claims which recites "greater than about" and does not provide a clear specific range of activity covered by the term "about". There is no definition. In regards to Applicant's argument that "exceeding about 10% per second" is not indefinite and the reference to MPEP 2173.05(b), this is not persuasive as the reference is incomplete. The MPEP addressed that the phrase "exceeding about 10% per second" for the stretch rate of plastic was not indefinite as it can be clearly accessed with a stopwatch. The MPEP goes on to state that that the court held that claims reciting "at least about " were invalid for indefiniteness there was there was nothing in the specification, prosecution history or the prior art to provide a clear specific range of activity covered by the term "about" in *Amgen, Inc. v. Chugai Pharmaceutical Co.*, 927 F.2d 1200, 18 USPQ2d 1016 (Fed. Cir. 1991). As a result, any amount applied for purposes of prosecution.

Accordingly, the rejection is maintained.

12. Claims 11-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite as Claim 11 is unclear as it is broader to an image analysis than the independent claim 1 which recites identification of the feeder with a high speed scanning laser ophthalmoscope and Claim 12 is unclear as it is to a different method of image analysis than the method recited in independent claim 1 which recites identification of the feeder with a high speed scanning laser ophthalmoscope. It does not allow one of skill in the art to ascertain the metes and bounds of the invention.

Claim 13 is cancelled, the rejection is moot.

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Applicant's arguments filed 5/5/2009 have been fully considered but they are not persuasive. Applicant's argument is that the amendment of "automated" rectifies the indefiniteness. This is not persuasive as it is subject to indefiniteness as addressed above. Applicant's arguments that claim 12 is to the use of fluorescein angiography in combination with the SLO. It is noted that the confusion is further compounded as the claims as originally filed recite the fluorescein angiograph and the SLO to be separate and distinct image analysis forms. The argument is also not persuasive as it is not commensurate in scope with the claim. The claim is not written in a manner to recite the combination, it is written to be the image analysis resulting in indefiniteness and is not further treated on its merits.

Accordingly, the rejection is maintained.

13. Claims 1-8, 10-11, 13-17, 24, 41-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Levy et al. (U.S. Pat. No. 5798349) in view of Jampol et al. (Treatment of Juxtafoveal and Extrafoveal Choroidal Neovascularization in the Era of Photodynamic Therapy With Verteporfin) and Roach (EyeNet Magazine March 2001).

Claim 13 is cancelled, the rejection is moot.

Applicant's arguments filed 5/5/2009 have been fully considered but they are not persuasive. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does

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not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. As Levy et al. teaches that photodynamic therapy for unwanted neovasculation in the eye is known, and Jampol teaches that photodynamic therapy (PDT) with verteporfin is well-known for treating patients with subfoveal choroidal neovascularization (CNV) and should be considered for the therapy of CNV that is not subfoveal in certain situations such as juxtafoveal and extrafoveal, and Roach teaches that real-time digital imaging systems such as for high-speed indocyanine green angiography (HSICG) coupled with a scanning laser ophthalmoscope can produce real time imaging and improve the results of feeder vessel treatment expressly stating that it's easier to treat a blood vessel you can see than one you can't. It is obvious to one of skill in the art to use a known therapy to treat its known conditions and treat the vessels at issue in any part of the eye including subfovea, juxtafoveal, and extrafoveal to address the condition and to utilize real-time digital imaging systems such as SLO, as it's easier to treat a blood vessel you can see than one you can't.

In regard to Applicant's assertion that juxtafoveal and extrafoveal treatment results in temporary relief but that the possibly growth of the scar and delayed changes is best explained by the fact that the feeder vessel are not identified or targeted by the method, this is not persuasive as the assertion is supposition and unsupported. As known in the art, CNV is difficult to treat and the area of Jampol cited by Applicant is directed to thermal photocoagulation not PDT. Also, Jampol does teach juxtafoveal and extrafoveal treatment as shown by several areas of Jampol including the title, that

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Jampol addresses that PDT and laser photocoagulation can be used in combination for these areas and even describes treatment of these areas with PDT with evaluation of the patient response.

Accordingly, the rejection is maintained.

14. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Levy et al. (U.S. Pat. No. 5798349) in view of Jampol et al. (Treatment of Juxtafoveal and Extrafoveal Choroidal Neovascularization in the Era of Photodynamic Therapy With Verteporfin) and Roach (EyeNet Magazine March 2001) as applied to claims 1-8, 10-11, 13-17, 24, 41-42 above, and in view of Levy et al. (U.S. Pat. No. 4920143).

Applicant's arguments filed 5/5/2009 have been fully considered but they are not persuasive. The arguments are directed Levy in view of Jampol in view of Roach which are addressed above. Applicant's argument that the references do not teach the topical administration of the photosensitizers is not persuasive. As addressed in the previous action, Levy (5798349) fully incorporates by reference Levy et al (4920143) which teaches that photosensitizing compounds can be administered for systemic or topical use in formulation which is well known in the art.

Accordingly, the rejection is maintained.

15. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Levy et al. (U.S. Pat. No. 5798349) in view of Jampol et al. (Treatment of Juxtafoveal and Extrafoveal Choroidal Neovascularization in the Era of Photodynamic Therapy With Verteporfin) and Roach (EyeNet Magazine March 2001) as applied to claims 1-8, 10-11,

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13-17, 24, 41-42 above, and in view of LumaCare (Press release - <http://lumacare.com/EMEA/pr3.html>).

Applicant's arguments filed 5/5/2009 have been fully considered but they are not persuasive. The arguments are directed Levy in view of Jampol in view of Roach which are addressed above.

Accordingly, the rejection is maintained.

16. Claims 1-8, 10-11, 13-17, 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sullivan (Jacksonville Medicine) in view of Jampol et al. (Treatment of Juxtafoveal and Extrafoveal Choroidal Neovascularization in the Era of Photodynamic Therapy With Verteporfin) and Roach (EyeNet Magazine March 2001).

Claim 13 is cancelled, the rejection is moot.

Applicant's arguments filed 5/5/2009 have been fully considered but they are not persuasive. Applicant's argument is directed to the argument that Sullivan does not suggest using a dose that is about 4x the standard recognized dose of 12J/cm² (e.g. about 50j/cm²) as addressed in the claims. This is not persuasive as addressed above, as the phrase "greater than about" is indefinite and any amount applied. In regards to Applicants argument that Jampol does not teach or suggest treatment in the juxtafoveal or extrafoveal area of the eye, and asserts that juxtafoveal and extrafoveal treatment results in temporary relief but since it can be followed by growth of the scar and delayed changes is best explained by the fact that the feeder vessels are not identified or targeted by the method. This is not persuasive as the assertion is supposition, unsupported, and as known in the art, CNV is difficult to treat and can relapse.

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Additionally the area of Jampol cited by Applicant is directed to thermal photocoagulation. Also, Jampol does teach juxtafoveal and extrafoveal treatment as shown by several areas of Jampol including the title, that Jampol addresses that PDT and laser photocoagulation can be used in combination for these areas and even describes treatment of these areas with PDT with evaluation of the patient response.

Accordingly, the rejection is maintained.

17. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sullivan (Jacksonville Medicine) in view of Jampol et al. (Treatment of Juxtafoveal and Extrafoveal Choroidal Neovasularization in the Era of Photodynamic Therapy With Verteporfin) and Roach (EyeNet Magazine March 2001) as applied for claims 1-8, 10-11, 13-17, 24, and further in view of Levy et al. (U.S. Pat. No. 4920143).

Applicant's arguments filed 5/5/2009 have been fully considered but they are not persuasive. The arguments are directed Sullivan in view of Jampol in view of Roach which are addressed above.

Accordingly, the rejection is maintained.

18. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sullivan (Jacksonville Medicine) in view of Jampol et al. (Treatment of Juxtafoveal and Extrafoveal Choroidal Neovasularization in the Era of Photodynamic Therapy With Verteporfin) and Roach (EyeNet Magazine March 2001) as applied for claims 1-8, 10-11, 13-17, 24 above, and in view of LumaCare (<http://lumacare.com/EMEA/pr3.html>).

Applicant's arguments filed 5/5/2009 have been fully considered but they are not persuasive. The arguments are directed Sullivan in view of Jampol in view of Roach which are addressed above.

Accordingly, the rejection is maintained.

19. Claims 41-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sullivan (Jacksonville Medicine) in view of Jampol et al. (Treatment of Juxtafoveal and Extrafoveal Choroidal Neovascularization in the Era of Photodynamic Therapy With Verteporfin) and Roach (EyeNet Magazine March 2001) as applied for claims 1-8, 10-11, 13-17, 24, and further in view of Miller et al. (U.S. Pat. No. 5707986).

Applicant's arguments filed 5/5/2009 have been fully considered but they are not persuasive. The arguments are directed Sullivan in view of Jampol in view of Roach which are addressed above.

Accordingly, the rejection is maintained.

Conclusion

20. Claims 1-12, 14-18, 24, 41-42 are rejected.

21. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GIGI HUANG whose telephone number is (571)272-9073. The examiner can normally be reached on Monday-Thursday 8:30AM-6:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Fredrick Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Primary Examiner, Art Unit 1612